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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/893,348	06/28/2001	Michal Eisenbach-Schwartz	EIS-SCHWARTZ-2A	1155

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EXAMINER
BUNNER, BRIDGET E

ART UNIT	PAPER NUMBER
1647	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/893,348	Applicant(s) EISENBACH-SCHWARTZ ET AL.
	Examiner Bridget E. Bunner	Art Unit 1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 March 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-44* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-44* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-25, drawn to a method for promoting nerve regeneration or conferring neuroprotection comprising administering NS-specific activated T cells, classified in class 424, subclass 93.7.

II. Claims 1-6, 26-30, and 41-43, drawn to a method for promoting nerve regeneration or conferring neuroprotection comprising administering a NS-specific antigen or an analog, classified in class 514, subclass 2.

III. Claims 1-6, 31-40 and 41-43, drawn to a method for promoting nerve regeneration or conferring neuroprotection comprising administering a peptide derived from an NS-specific antigen, classified in class 514, subclass 2.

IV. Claims 1-6, drawn to a method for promoting nerve regeneration or conferring neuroprotection comprising administering a nucleotide sequence encoding a NS-specific antigen, classified in class 514, subclass 44.

V. Claims 1-6, drawn to a method for promoting nerve regeneration or conferring neuroprotection comprising administering a nucleotide sequence encoding a peptide derived from a NS-specific antigen, classified in class 514, subclass 44.

VI. Claims 1-6, drawn to a method for promoting nerve regeneration or conferring neuroprotection comprising administering any combination of claim 1 (a)-(e), classification dependent upon combination.

VII. Claims 1-25, drawn to a method for preventing or inhibiting neuronal degeneration comprising administering NS-specific activated T cells, classified in class 424, subclass 93.7.

VIII. Claims 1-6, 26-30, and 41-43, drawn to a method for preventing or inhibiting neuronal degeneration comprising administering a NS-specific antigen, classified in class 514, subclass 2.

IX. Claims 1-6, 31-40, and 41-43, drawn to a method for preventing or inhibiting neuronal degeneration comprising administering a peptide derived from an NS-specific antigen, classified in class 514, subclass 2.

X. Claims 1-6, drawn to a method for preventing or inhibiting neuronal degeneration comprising administering a nucleotide sequence encoding a NS-specific antigen, classified in class 514, subclass 44.

XI. Claims 1-6, drawn to a method for preventing or inhibiting neuronal degeneration comprising administering a nucleotide sequence encoding a peptide derived from a NS-specific antigen, classified in class 514, subclass 44.

XII. Claims 1-6, drawn to a method for preventing or inhibiting neuronal degeneration comprising administering any combination of claim 1 (a)-(e), classification dependent upon combination.

XIII. Claim 44, drawn to a method for preventing or inhibiting neuronal degeneration comprising administering a composition for upregulating B7.2 co-stimulatory molecule or genetically manipulating B7.2 co-stimulatory molecule, classification dependent upon composition.

The inventions are distinct, each from the other because of the following reasons:

a. Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to different methods, restriction is deemed to be proper because these methods constitute patentably distinct inventions for the following reasons. Inventions I-XIII are different methods because they require different ingredients, process steps, and endpoints. Groups I-XIII are different methods requiring different method steps, wherein each is not required, one for another. For example, Invention I requires search and consideration of efficacy of therapy of T cell administration to promote nerve regeneration, which is not required by the other inventions, which is not required by the other inventions. Invention II requires search and consideration of efficacy of therapy of NS-specific antigen administration to promote nerve regeneration, which is not required by the other inventions. Invention III requires search and consideration of efficacy of therapy of administration of a peptide derived from a NS-specific antigen to promote nerve regeneration, which is not required by the other inventions. Invention IV requires search and consideration of efficacy of therapy of administration of a nucleotide sequence encoding a NS-specific antigen to promote nerve

regeneration, which is not required by the other inventions. Invention V requires search and consideration of efficacy of therapy of administration of a nucleotide sequence encoding a peptide derived from a NS-specific antigen to promote nerve regeneration, which is not required by the other inventions. Invention VI requires search and consideration of efficacy of therapy of administration of any combination of T cells, peptides, or nucleotide sequences to promote nerve regeneration, which is not required by the other inventions. Invention VII requires search and consideration of efficacy of therapy of T cell administration to prevent or inhibit neuronal degeneration, which is not required by the other inventions. Invention VIII requires search and consideration of efficacy of therapy of NS-specific antigen administration to prevent or inhibit neuronal degeneration, which is not required by the other inventions. Invention IX requires search and consideration of efficacy of therapy of administration of a peptide derived from a NS-specific antigen to prevent or inhibit neuronal degeneration, which is not required by the other inventions. Invention X requires search and consideration of efficacy of therapy of administration of a nucleotide sequence encoding a NS-specific antigen to prevent or inhibit neuronal degeneration, which is not required by the other inventions. Invention XI requires search and consideration of efficacy of therapy of administration of a nucleotide sequence encoding a peptide derived from a NS-specific antigen to prevent or inhibit degeneration, which is not required by the other inventions. Invention XII requires search and consideration of efficacy of therapy of administration of any combination of T cells, peptides, or nucleotide sequences to prevent or inhibit neuronal degeneration, which is not required by the other inventions. Invention XIII requires search and consideration of efficacy of therapy of administration of a compound to upregulate B7.2 co-stimulatory molecule or genetically manipulating B7.2 co-stimulatory molecule, which is not required by the other inventions.

2. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their different classification, separate search requirements, and recognized divergent subject matter, restriction for examination purposes as indicated is proper.

3. This application contains claims directed to the following patentably distinct species of the claimed invention:

A method for promoting nerve regeneration or preventing/inhibiting neuronal degeneration in the central nervous system or peripheral nervous system for ameliorating the effects of :

a. injury

b. disease

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, no claims are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after

the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

4. This application contains claims directed to the following patentably distinct species of the claimed invention:

A method for promoting nerve regeneration or preventing/inhibiting neuronal degeneration in the:

c. central nervous system

d. peripheral nervous system

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, no claims are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

5. This application contains claims directed to the following patentably distinct species of the claimed invention:

A method for promoting nerve regeneration or preventing/inhibiting neuronal degeneration, wherein the treatment ameliorates the effects of the following injuries and diseases:

e. spinal cord injury

f. blunt trauma

g. penetrating trauma

h. hemorrhagic stroke

i. ischemic stroke

j. damages caused by surgery

k. a degenerative process occurring in the gray/white matter

l. Diabetic neuropathy

m. senile dementia

o. Alzheimer's disease

p. Parkinson's disease
q. facial nerve (Bell's) palsy
r. glaucoma
s. Huntington's chorea
t. amyotrophic lateral sclerosis
u. status epilepticus
v. non-arteritic optic neuropathy
w. vitamin deficiency
x. invertebral disc herniation
y. prion diseases
z. carpal tunnel syndrome
aa. peripheral neuropathies associated with various diseases

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 17-44 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

6. This application contains claims directed to the following patentably distinct species of the claimed invention:

A method for promoting nerve regeneration or preventing/inhibiting neuronal degeneration comprising administering NS-specific activated T cells, wherein the T cells:

bb. have been sensitized to a NS-specific antigen

cc. have been sensitized to a peptide derived from a NS-specific antigen

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-10 and 25-44 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after

the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

7. This application contains claims directed to the following patentably distinct species of the claimed invention:

A method for promoting nerve regeneration or preventing/inhibiting neuronal degeneration comprising administering NS-specific activated T cells or a NS-specific antigen, wherein the NS-specific antigen is:

dd. MBP

ee. myelin oligodendrocyte glycoprotein

ff. proteolipid protein

gg. myelin-associated glycoprotein

hh. S-100

ii. β-amyloid

jj. Thy-1

kk. P0

ll. P2

mm. a neurotransmitter receptor

nn. Nogo-A

oo. Nogo-B

pp. Nogo-C

qq. Nogo receptor

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-11, 15-26, and 31-44 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

8. This application contains claims directed to the following patentably distinct species of the claimed invention:

A method for promoting nerve regeneration or preventing/inhibiting neuronal degeneration comprising administering NS-specific activated T cells or a NS-specific antigen, wherein the NS-specific antigen is an epitope derived from:

rr. MBP

ss. MOG

tt. Nogo

uu. Nogo receptor

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-16, 25-32 and 41-44 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to

be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

9. This application contains claims directed to the following patentably distinct species of the claimed invention:

A method for promoting nerve regeneration or preventing/inhibiting neuronal degeneration comprising administering a NS-specific antigen is administered:

ww. intravenously

xx. intrathecally

yy. intramuscularly

zz. intradermally

aaa. topically

bbb. subcutaneously

ccc. mucosally

ddd. oral

eee. intranasal

fff. buccal

ggg. vaginal

hhh. rectal

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-40 and 44 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

If Applicant elects Groups I-XII, one species from the disease vs. injury group must also be chosen to be considered fully responsive.

If Applicant elects Groups I-XIII, one species from the nervous system group must also be chosen to be considered fully responsive.

If Applicant elects Groups I-XII, one species from the specific type of disease/injury group must also be chosen to be considered fully responsive.

If Applicant elects Groups I-XII, one species from the T cell sensitization group must also be chosen to be considered fully responsive.

If Applicant elects Groups I-XII, one species from the NS-specific antigen group must also be chosen to be considered fully responsive.

If Applicant elects Groups I-XII, one species from the epitope derivation group must also be chosen to be considered fully responsive.

If Applicant elects Groups I-XII, one species from the administration group must also be chosen to be considered fully responsive.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bridget E. Bunner whose telephone number is (703) 305-7148. The examiner can normally be reached on 8:30-5:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (703) 308-4623. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 872-9305.

Gary J. Kunz

GARY KUNZ
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

BEB
Art Unit 1647
September 30, 2002